

~~alpha tricalcium phosphate by sintering, wherein silicon entities are added in solution to the hydroxyapatite substance before sintering which stabilize and insolubilize the formed alpha tricalcium phosphate within the phosphate phases.~~

REMARKS

This is in response to the Official Action mailed November 8, 1999, in the above-referenced application. Claims 1 to 37 are before the Examiner. Applicants note with appreciation the indication by the Examiner that Claim 37 is allowed and that Claims 10, 19 and 20 would be allowable if rewritten in independent form. Claims 10 and 19 are amended herein to present these claims in independent form. This amendment also overcomes the rejection of Claim 10 as lacking proper antecedent basis. Applicants accordingly request an indication of the allowance of Claims 10 and 19. Because Claim 20 is dependent on a now allowable base claim, Applicants further request an indication of the allowance of Claim 20 as well. The remaining issues raised in the Official Action are addressed below in the order set forth therein.

Objections to the Specification

The Office Action objects to the present application as not containing an abstract of the disclosure as required by 37 CFR 1.72(b). Attached herewith please find an abstract in accordance with 37 CFR 1.72(b).

The Office Action also objects to the terminology "said silicon entities" in Claim 10 as lacking antecedent basis. As noted above, the amendment to Claim 10 overcomes this.

In view of the foregoing, Applicants respectfully request withdrawal of the objections to the specification.

Claim Rejections under 35 USC § 102

Claims 1-3, 5-8, 11-18, 21-23, 31 and 33-36 are rejected under 35 USC §§102(a) or (b) as being anticipated by Davies (WO 94/26872). Applicants respectfully disagree with the Examiner with respect to both the §§ 102(a) and/or (b) rejection and submit that the Davies reference does not anticipate the noted claims. In this regard, the Davies reference is directed to a calcium

phosphate based thin film for culturing bone cells thereon. The Davies publication does not specify the make up of the thin film therein, other than to note that the thin film comprises both calcium hydroxyapatite and tricalcium phosphate in different ratios. Indeed, as the Office acknowledges, Davies is completely silent as to the provision of stabilized calcium phosphate phases.

The Office Action states that Davies uses a quartz substrate. Applicants submit, however, that this is not the same as teaching the compositions as claimed. In this regard, Davies states on page 8 that a quartz substrate was selected due to its thermally tolerant properties. Davies further states that other materials, including metals, polymers or ceramic materials, may also be used. Davies always refers to the substrate as a "substrate" which provides support for the thin film and which can allow for certain analytical assessment of the film after the culture of the cells. Therefore, Davies nowhere teaches or suggests the effect a quartz substrate would have, if any, on the thin film. Its sole contemplated use is to provide a suitable physical substrate that could be sintered and could be used in analytical testing.

This is further supported by the fact that Davies teaches the use of other materials such as metals, polymers or ceramics as a support. In these circumstances, where, for example, silicon would not be present, Davies nowhere identifies a separate and additional use of a stabilizing entity as necessary. This further illustrates that Davies does not teach the function of quartz in the compositions, much less its use as a stabilizing entity.

In contrast to Davies, the present invention recognizes that certain stabilizing entities are required to stabilize the calcium phosphate composition and prevent its degradation in physiological fluids. The stabilizing entities stabilize the tricalcium phosphate to form an insoluble composition with a morphology for supporting and encouraging bone cell activity thereon. The use of stabilizing entities to stabilize and insolubilize the calcium phosphate phases was not taught by Davies and therefore Davies cannot be said to anticipate the presently claimed invention.

Furthermore, the claimed invention is not inherent from the Davies reference. The Office Action notes that in one embodiment Davies teaches a method for making a calcium phosphate under suitable sintering temperatures on quartz. This, however, by no means inherently teaches the claimed compositions in which the calcium phosphate phases are stabilized. Discovery of the presently claimed invention required diligent effort on the part of the inventors, especially since Davies did not teach the use of the quartz substrate for anything but as a "physical substrate" which could withstand sintering temperatures. That is, Davies was only interested in having a supporting structure. Further, Davies never recognized that the production of a sol-gel would not work for the culture of bone cells if the quartz substrate was not used. Therefore, the Davies reference does not teach or suggest anything about the chemical role of quartz. In fact, Davies teaches away from the stabilization of calcium phosphate phases since Davies suggests the use of other materials such as ceramics and the like that do not contain any suitable stabilizing entities.

In contrast, the present inventors found that the stabilizing entities had to be deliberately mixed with the hydroxyapatite sol-gel in order to provide the bioactive artificial stabilized sintered composition. Once the stabilizing entities were added to the hydroxyapatite and sufficiently mixed therein, various products could be made such as powders, thick coatings and three-dimensional bulk materials.

For these reasons *supra*, Applicants submit that Davies does not teach the claimed invention, either explicitly or inherently and accordingly request withdrawal of this rejection.

Claims 1-4, 7, 9, 12-14, 17, 19, 22, 23, 31 and 34 are also rejected under 35 USC § 102(b) as being anticipated by Kasuga et al (U.S. 5,232,878). Again, the Applicants respectfully disagree with the Examiner. Kasuga is directed to a physical dispersion of crystallized glass or calcium phosphate within a skeleton of zirconia, which provides for increased mechanical properties. Kasuga teaches "partially stabilized zirconia" by which is meant that the zirconia is prepared to attain high strength and high toughness with respect to stress-induced transformation (column 6, lines 38-44) for use as a biomaterial for artificial bones and dental implants. The composition does not support active bone cell activity thereon leading to bone remodeling.

Kasuga does not teach a bioactive artificial stabilized sintered composition for supporting bone cell activity thereon. For these reasons, this reference also does not anticipate the presently claimed invention, and Applicants request withdrawal of this rejection as well.

Claim Rejections under 35 USC §103

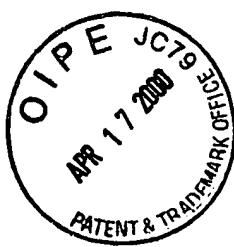
Claims 9, 24-30 and 32 are also rejected under 35 USC § 103(a) as being obvious in view of the teachings of Davies, cited above. For the reasons as provided *supra*, Applicants submit that the claimed invention is also not rendered obvious by the teachings of Davies. The basis for the presently claimed invention is the stabilized calcium phosphate phases which form the basis for the use of the bioactive composition in various applications. Davies does not suggest that the calcium phosphate phases are stabilized by any type of entities in any sense. Again, Davies teaches away from the invention of stabilized calcium phosphate phases because Davies suggests using other materials for substrates such as ceramics and polymers that would not provide any type of stabilizing entity. For these reasons, the presently claimed invention is not obvious in view of the Davies reference.

Conclusions

In summary, Applicants respectfully submit that the claimed invention is both novel and nonobvious and accordingly request withdrawal of the all rejections under 35 USC §§ 102(a) or (b) and USC § 103(a).

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

In re: Pugh et al.
Appl. No.: 09/029,872
Filed: June 29, 1998
Page 6



therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

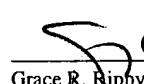
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